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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,052	11/20/2001	Holger Bock	2727-154	8509

7590 09/20/2005

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EXAMINER	
LEWIS, PATRICK T	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,052	BOCK ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2005 has been entered.

Applicant's Response Dated July 1, 2005

2. In the Response filed July 1, 2005, claims 1-10 were amended. Claims 1-10 are pending. An action on the merits of claims 1-10 is contained herein below.

3. The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Egholm et al. J. Am. Chem. Soc., 1992, Vol. 114, 1895-1897 (Egholm) in combination with Varadarajan et al. Bioconjugate Chem., 1991, Vol. 2, 242-253 (Varadarajan) and Kane et al. J. Org. Chem., 1993, Vol. 58, 991-992 (Kane) has been withdrawn in view of applicant's arguments dated July 1, 2005 and the declaration under 37 C.F.R. 1.132 dated July 1, 2005. The declaration pointed out that the prior art did not teach or suggest modifying the PNA backbone with a phosphonic acid, phosphite ester, or carbaborane radical as instantly claimed. The declaration further showed unexpected results in terms of the solubility of instantly claimed PNA derivatives.

4. The rejection of claims 1-3, 5 and 10 under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. US 5,846,741 (Griffiths) in combination with Varadarajan et al. Bioconjugate Chem., 1991, Vol. 2, 242-253 (Varadarajan) has been withdrawn in view of applicant's arguments dated July 1, 2005 and the declaration under 37 C.F.R. 1.132 dated July 1, 2005. The declaration pointed out that the prior art did not teach or suggest modifying the PNA backbone with a phosphonic acid, phosphite ester, or carbaborane radical as instantly claimed. The declaration further showed unexpected results in terms of the solubility of instantly claimed PNA derivatives.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

1. the breadth of the claims;
2. the nature of the invention;
3. the state of the prior art;
4. the level of one of ordinary skill in the art;
5. the level of predictability in the art;
6. the amount of direction provided by the inventor;
7. the existence of working examples; and
8. the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 10 is drawn to a method for cancer therapy using a compound as defined in claim 1 comprising diagnosing a cancerous condition and applying an instantly claimed PNA derivative as described in claim 1.

Undue experimentation is required to determine which, if any, of the instantly claimed compounds are effective in treating cancer broadly as instantly claimed. There has not been provided adequate guidance in the written description for accomplishing such, as none of the instantly claimed compounds were assessed for efficacy in treating a single cancer, out of the numerous known cancers in the art. Without guidance as to what modified PNA derivatives are effective for cancer treatment, as well as the identification of the specific cancers for which said derivative is effective, undue trial and error experimentation would be required to screen through the myriad of different chemical molecules to determine those with the desired pharmacological activity.

There are no teachings in the prior art which would lead one of ordinary skill in the art at the time the invention was made to predict that applying one of the instantly claimed compounds was effective in the treatment of a specific cancer or cancer broadly. While certain agents and compositions are known to treat certain forms of cancer, no effective agent or composition has been found for the treatment of all cancer types. Griffiths et al. US 5,846,741 (Griffiths) is representative of the state of the art at the time of the invention. Griffiths teaches methods for targeting boron atoms to tumor cells for effecting boron neutron capture therapy (BNCT). Griffith teaches that 300-1000 boron atoms per tumor cell are necessary to sustain a cell-killing nuclear reaction. Griffiths further teaches that success in BNCT of cancer requires methods for localizing a high concentration of boron-10 at tumor sites, while leaving non-target organs essentially boron-free. The instant specification fails to teach how a high concentration of boron atoms is selectively localized in target organs.

It is noted that while there are some working examples drawn to the synthesis of a number of the instantly claimed PNA derivatives, no data is presented in support of applicant's claim of cancer treatment. No data is presented showing greater selectivity of the instant derivatives with respect to accumulation in target versus non-target organs. No data relating to cytotoxicity is presented. The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to enable the use of the instant PNA derivatives for cancer treatment. It is noted that Law requires that the disclosure of an

application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). A broad claim requires a correlatively broad and sufficient disclosure to support it. There is nothing inherently wrong with defining some part of an invention in functional terms; however, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 6 and 9, the parenthetical phrases "(3-8 ring atoms)", "(3-6 ring atoms)", and "(n = 0 to 3, X = F, Cl, Br, I)" render the claims indefinite because it is

unclear whether the limitations within the parentheses are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 2, the phrase "compound comprising...compounds of the formula W-U-Z" renders the claim indefinite as it is unclear how the up to 50 compounds of formula W-U-Z are connected to form the instant compound. Additionally variables W, U, and Z are not defined.

Claim 7 recites the limitation "R^{17} is not a hydrogen atom and is bound to a solid phase" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 9, the phrase "converted in known manner" renders said claim indefinite. The claim fails to particularly point out which moieties are converted, how they are converted, or what they are converted to.

Regarding claim 10, the claim is indefinite because applicant has failed to particularly point out the methodological steps. It is unclear what the term "applying" means in the context of the instant claim. Furthermore, it is unclear where or to what the compound is applied.

Conclusion

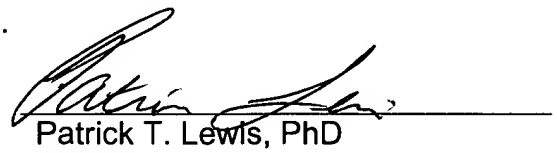
9. Claims 1-10 are pending. Claims 1-10 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patrick T. Lewis, PhD
Examiner
Art Unit 1623

ptl